February 22, 2016

Ms. Patrice Drew
Regulatory Affairs Liaison
Office of Inspector General
Department of Health and Human Services
Cohen Building, Room 5541C
330 Independence Avenue SW
Washington, DC 20201

RE: HHS-OIG-124-N: Solicitation of New Safe Harbors and Special Fraud Alerts

Dear Ms. Drew:

The Healthcare Leadership Council (HLC) respectfully submits these comments in connection with the Office of Inspector General's notice of intent to develop regulations on safe harbor provisions under the Federal anti-kickback statute of the Social Security Act. We applaud the important and timely nature of this solicitation for new or modified safe harbor provisions. We believe that modifications to some of these provisions are important to facilitate the spread of new, HHS-championed, care delivery and payment models in the private sector.

HLC is a coalition of chief executives from all disciplines within American healthcare. It is the exclusive forum for the nation’s healthcare leaders to jointly develop policies, plans, and programs to achieve their vision of a 21st century health system that makes affordable, high-quality care accessible to all Americans. Members of HLC—hospitals, academic health centers, health plans, pharmaceutical companies, medical device manufacturers, biotech firms, health product distributors, pharmacies, post-acute care providers, and information technology companies—advocate measures to increase the quality and efficiency of healthcare by emphasizing wellness and prevention, care coordination, and the use of evidence-based medicine, while utilizing consumer choice and competition to enhance value.

HLC created the National Dialogue for Healthcare Innovation (NDHI) to allow industry, patients, employers, academicians, and government to examine, discuss, and build consensus on how to address the most important issues affecting the course of 21st century healthcare progress. On March 2, 2015, NDHI convened an unprecedented summit with leaders of more than 70 of the most influential public and private organizations in
healthcare to identify the barriers impeding progress toward a high-value, innovation-driven healthcare system, and how to remove those barriers. This was a rare meeting focused not on a single, narrow healthcare issue, but rather on how to create a sustainable system equipped to address persistent cost and quality challenges.

NDHI participants have considered whether changes to the current legal framework are needed to make it more compatible with new care delivery and payment models. As such, they agree that these value-based alternative payment models (APMs) are restrained by outdated federal and state statutes and regulations that were designed for a fee-for-service care model. Important care coordination and patient engagement aspects of APMs could inadvertently trigger fraud and abuse concerns under the Federal Anti-Kickback Statute and Physician Self-Referral (Stark) Law. HLC and NDHI participants believe that these challenges should be addressed to support healthcare delivery system transformation while retaining appropriate protections against fraud and abuse.

Please find enclosed with this letter initial recommendations on suggested regulatory changes to the federal anti-Kickback statute and physician self-referral (Stark) regulations to foster integrated care delivery and APMs. These recommendations achieved broad consensus support through HLC’s NDHI initiative.

It is also important to note that our shared goal of moving the U.S. healthcare system toward quality-driven, value-based care delivery and payment models will require broader regulatory changes than those contained within these comments. Relevant laws and regulations include the Civil Monetary Penalties (CMP) Law, including beneficiary inducement and gainsharing provisions; the Civil and Criminal False Claims Acts (FCA); HIPAA; antitrust and tax laws; and state laws that overlap with, mirror, or relate to these federal laws.

Please contact Tina Grande, HLC’s SVP for Policy at tgrande@hlc.org or (202) 449-3433 with any questions about the comments in this letter.

Sincerely,

Mary R. Grealy
President

Enclosure
Health System Transformation:  
Possible Changes to the Federal Anti-Kickback Statute and Physician Self-Referral (Stark) Law to Foster Integrated Care Delivery and Payment Models

Priority Options¹
December 17, 2015

As the U.S. healthcare system continues to move toward quality-driven, value-based care delivery and payment models, policy and implementation challenges arise as these models may implicate the federal fraud and abuse legal framework. These models may align financial interests in ways that trigger fraud and abuse concerns. Stakeholders across the healthcare system are considering whether changes to the current legal framework are needed to make it more compatible with healthcare delivery system transformation while retaining appropriate protections against fraud and abuse.

This list represents a working draft of potential priority regulatory modifications to the Federal Anti-Kickback Statute and Physician Self-Referral (Stark) Law that would better support innovative and integrated care delivery and payment models. ² It is not intended to be, nor should it be construed, as an exhaustive analysis of the universe of potential modifications to these laws or other related federal and state fraud and abuse laws. Rather, the potential options are based on discussions with the Healthcare Leadership Council and representatives from the National Dialogue for Healthcare Innovation and their priorities as referenced during those discussions.

¹ This priority list is accompanied by a separate memorandum, Health System Transformation: Possible Changes to the Federal Anti-Kickback Statute and Physician Self-Referral (Stark) Law to Foster Integrated Care Delivery and Payment Models, that addresses both the priority options as well as a fuller list of potential options. The memorandum, prepared by Jane Hyatt Thorpe, JD and Elizabeth Gray, JD, MHA, CHC of George Washington University Milken Institute School of Public Health, was submitted to the Healthcare Leadership Council on December 17, 2015.

² New care delivery and payment models potentially implicate many federal and state statutes and regulations. These include the Federal Anti-Kickback Statute; Physician Self-Referral (Stark) Law; Civil Monetary Penalties (CMP) Law, including beneficiary inducement and gainsharing provisions; the Civil and Criminal False Claims Acts (FCA); HIPAA; antitrust and tax laws; and state laws that overlap with, mirror, or relate to these federal laws. This memo addresses the Federal Anti-Kickback Statute and the Physician Self-Referral (Stark) Law, as primarily and respectively enforced by the U.S. Department of Health and Human Services (HHS) Office of Inspector General (OIG) and Centers for Medicare & Medicaid Services (CMS). While this paper does not address the other federal and state laws noted above, it is particularly important to note the relationship between the Federal Anti-Kickback Statute and the Civil Monetary Penalties (CMP) Law as they relate to both beneficiary inducement (i.e., providing anything of value to a patient in order to encourage the patient to utilize a particular provider, device, or pharmaceutical) and gainsharing (i.e., providing shared savings to providers). As such, when considering potential changes to the Anti-Kickback Statute, stakeholders should also consider related changes to the CMP Law to ensure consistency in interpretation and application across both laws.
The following priority options, were selected by the Healthcare Leadership Council and the National Dialogue for Healthcare Innovation initiative based on the following criteria:

**Feasibility:** Willingness of Congress, CMS and/or OIG to address

**Impact:** Potential to alleviate and/or eliminate perceived and/or real barriers to developing and implementing new models of care delivery and payment based on fraud and abuse framework

**Timeliness:** Whether meaningful action may/can be taken in the next 6-12 months

**Regulatory Options**

- Create Anti-Kickback Statute and Stark Law waivers for all ACOs that meet certain conditions, whether those ACOs are participating in the Medicare Shared Savings Program (MSSP) or not.

- Extend existing Anti-Kickback Statute and Stark Law exceptions for donation and financial support of EHR software, related technologies, and training beyond 2021. As part of an extension, ensure range of relevant and appropriate technologies are included based on the evolving technological environment.

- Clarify how to establish, document, and apply the “volume or value of referrals” standard within the changing healthcare payment environment.

- Expand and revise definition of fair market value to account for new payment models that incentivize performance\(^3\) (e.g., payment for consulting services or other professional services, such as medical directorships).

- Eliminate or redefine the “one purpose” test for Anti-Kickback Statute liability and replace it with a balancing test that would require the OIG to prove either increased cost or actual harm to a patient.\(^4\) This would potentially allow, for example, arrangements where providers and/or medical device or pharmaceutical manufacturers provide items or services of value to patients to assist with prescription medication adherence or access to healthcare services. The OIG could assess the arrangement’s overall impact on quality of care and weigh these benefits against the potential risk of fraud and abuse to determine whether the transaction is permissible, regardless of whether one purpose of the arrangement is potentially problematic.

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